

REMARKS

Entry and consideration of the foregoing amendments is respectfully requested. Previously withdrawn claims 1, 5 and 20-29 are newly canceled. These claims were held by the Examiner as being directed to non-elected inventions. None of the currently pending claims are newly amended. No new matter has been added by the present amendments. Therefore, claims 2-4 and 6-19 are presently under examination.

RESPONSE

Claim Rejections – 35 USC § 112, First Paragraph – Written Description

Claims 2-4 and 6-19 stand rejected under 35 USC § 112, first paragraph, as allegedly failing to comply with the written description requirement. More specifically, the Office Action alleges that “Applicant has conveyed with reasonable clarity to those skilled in the art that, as of the filing date sought, Applicant was in possession of alfalfa varieties CW 75046, CW 83201, CW 85029 and CW 95026 and not each and every alfalfa plant with the claimed characteristics as is broadly claimed” (page citations omitted).

Applicants respectfully request that the Examiner provide them with the statute, rule and/or case law that supports his contention that Applicants are somehow required to demonstrate that they were in possession of “each and every alfalfa plant with the claimed characteristics” at the time of filing. This requirement is clearly preposterous on its face and possibly calls into question the validity of thousands if not millions of issued U.S. patents that are not in compliance with this Examiner-dictated requirement.

Applicants note (again) that they are not claiming just any *Medicago sativa* alfalfa plant with faster recovery and more erect stems, but rather are claiming *Medicago sativa* alfalfa varieties with 8% or greater faster recovery after spring green-up or after harvest coupled with having 15% or greater more erect stems at late bloom when compared to specific commercial check varieties, wherein such checks were the best commercial check varieties available at the time of the present invention. Therefore, Applicants are not claiming just any *Medicago sativa* alfalfa plants as alleged by the Examiner, but rather are claiming *Medicago sativa* alfalfa varieties with specific and clearly defined traits hitherto unknown to those skilled in the art of alfalfa breeding.

Vas-Cath Inc. v. Mahurkar, which is relied upon by the Examiner to support this rejection, held that “to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.” *Id.* 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). See, also, the US PTO’s position on the teachings of this case as provided at M.P.E.P. § 2163.02. As discussed in great detail in the Response/Amendment filed in response to the first Non-Final Office Action, Applicants have clearly met the standard for the written description requirement set forth in *Vas-Cath Inc. v. Mahurkar*. The presently pending claims clearly set forth exactly how a potential infringer can determine whether a particular *Medicago sativa* alfalfa variety falls within the metes and bounds of the claimed invention, wherein the claimed elements of those metes and bounds are clearly and explicitly set forth in the as-filed specification as explained at page 9 in the Amendment and Response Under 37 C.F.R. § 1.111.

Furthermore, the as-filed specification provides detailed written descriptions of the development of four very different and distinct *Medicago sativa* alfalfa varieties derived from diverse genetic background, wherein each of these varieties clearly meet the limitations of the claims (see, for example, Example 3, pages 25-45). Anyone skilled in the art of alfalfa variety development can follow the procedures described in the as-filed specification to develop additional varieties which fall within the limitations of the claimed genus of alfalfa varieties with 8% or greater faster recovery after spring green-up or after harvest and 15% or greater more erect stems at late (i.e., 75% bloom) when compared to the specific adapted check alfalfa varieties as set forth in the claims. Alternatively, one skilled in the art can use any of Applicant’s inventive, disclosed and deposited alfalfa varieties to develop additional alfalfa varieties which meet the claimed limitations. In fact, Applicants have done exactly this (i.e., developed additional *Medicago sativa* alfalfa varieties with the claimed traits by using the exemplary, deposited varieties as a source of genetic material in the breeding regime leading to such additional varieties). Applicants would be pleased to supply the Examiner with examples of such additional varieties via Declaration if the Examiner believes that would be helpful in gaining allowance of the pending claims. Moreover, one skilled in the art can follow the procedures described in the as-filed specification using the same parental populations that were used to

develop the exemplary, deposited varieties as described in the as-filed specification to develop additional alfalfa varieties which meet the claimed limitations. In fact, Applicants have done exactly this (*i.e.*, developed additional *Medicago sativa* alfalfa varieties with the claimed traits by using the same parental populations used to develop the exemplary, deposited varieties as described in the as-filed specification as the genetic source material in the breeding regime leading to such additional varieties). Applicants would be pleased to supply the Examiner with examples of such additional varieties via Declaration if the Examiner believes that would be helpful in gaining allowance of the pending claims. Applicants believe that it is a clear error for the Examiner to maintain this rejection because the as-filed specification conveys the invention to the public with reasonable clarity, Applicants' were clearly in possession of the invention at the time of filing, the as-filed specification demonstrates that Applicants had multiple examples of their claimed subject matter in hand at the time of filing, and that invention is now what is being claimed.

Claim Rejections – 35 USC § 112, First Paragraph – Enablement

Next, claims 2-4 and 6-19 stand rejected under 35 USC § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Office action states the following in summarizing this rejection (paragraph bridging pages 6-7):

“Given the breadth of the claims, the lack of guidance regarding the use of uncharacterized French lines in the initial step of the methods disclosed in the specification on how to make and use the claimed invention, the amount of experimentation for one skilled in the art to determine which of the multitude of uncharacterized French lines would possess the claimed characteristics, and the unpredictability of the development of improved alfalfa varieties it would require undue trial and error experimentation for one skilled in the art to make and use the claimed invention.”

As an initial matter, Applicants note that “[T]he examiner’s analysis must consider all of the evidence related to each of these factors, and any conclusion of nonenablement must be

based on the evidence as a whole” (MPEP 2164.01(a), citing *In re Wands* 858 F.2d 737, 740 8 USPQ2d at 1404, 1407). The Examiner’s rejection does not meet this standard and we believe is a clear error.

Applicants respectfully direct the Examiner’s attention to the very detailed and complete analysis of each of the eight considerations in *In re Wands*, 858F 2d 731, 9 USPQ2d 1400 (Fed. Cir. 1988), as set forth at pages 14-19 of the Amendment and Response Under 37 C.F.R. § 1.111 filed in response to the first Non-Final Office Action. The Examiner seems to pick-and-choose a different subset of the Wands factors with each office action. Now the Examiner appears only concerned with the following *Wands* factors: (1) breadth of the claims; (2) the quantity of experimentation needed to make or use the invention based on the content of the disclosure; and (3) the level of predictability in the art.

Breadth of the claims. The Examiner is respectfully requested to review the detailed response to this factor provided in the Amendment and Response Under 37 C.F.R. § 1.111 at pages 14-16, which is herein incorporated by reference in its entirety. If the Examiner’s extremely broad-stroked rejection is maintained, then there appears to be no way any inventor of a “genus” plant breeding invention can ever obtain claims to anything broader than a narrow “species” claim. Clearly, that is not the standard set by Congress, the courts or the U.S. Patent & Trademark Office and the Examiner has committed a clear error.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure. “[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance.” *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). Conventional plant breeding schemes involve a number of well-known steps and can require a number of growing seasons to accomplish. This is well known and accepted in the art. The as-filed specification provides sufficient direction and guidance as to how one skilled in the art could develop the alfalfa varieties of the present invention. See, Examples 1-3. Furthermore, Applicants have deposited representative alfalfa varieties of the claimed invention which could be used by one skilled in the art to develop additional alfalfa varieties with the claimed traits using standard plant breeding protocols. As discussed supra, Applicants have developed additional *Medicago sativa* alfalfa varieties with the claimed traits by using the exemplary, deposited varieties as a source of genetic material in the breeding regime

leading to such additional varieties. In addition, Applicants have developed additional *Medicago sativa* alfalfa varieties with the claimed traits by using the same parental populations used to develop the exemplary, deposited varieties as described in the as-filed specification as the genetic source material in the breeding regime leading to such additional varieties. Applicants would be pleased to supply the Examiner with examples of such additional varieties via Declaration if the Examiner believes that would be helpful in gaining allowance of the pending claims. For these reasons, the quantity of experimentation needed to be performed by one skilled in the art is customary and expected for a plant breeding invention such as the presently claimed invention. The use of such standard plant breeding procedures is clearly not undue experimentation.

The level of predictability in the art. The Examiner is respectfully requested to review the response to this factor provided in the Amendment and Response Under 37 C.F.R. § 1.111 at pages 17-18, which is herein incorporated by reference in its entirety. As explained therein, alfalfa breeding is a predictable art where, like here, Applicants have provided a clear and detailed plant breeding roadmap to accomplishing the claimed invention. Furthermore, Applicants have deposited varieties with the very traits being claimed where such varieties can and have been used to develop additional varieties with the claimed traits, as discussed supra. Surely, in view of Applicants' disclosure, the claimed invention is predictable and the Examiner's rejection is a clear error.

For each and all of the reason set forth above, the presently claimed invention complies with the enablement requirement and the Examiner is therefore respectfully requested to withdraw the rejection.

Claim Rejections – 35 USC § 102(b)

Claims 2-4 and 6-19 are newly rejected under 35 USC § 102(b) as allegedly being anticipated by or, in the alternative, under 35 USC § 103 as obvious over Cluff *et al.* (US Patent No. 6,143,951). The Examiner asserts that “Cluff *et al.* teach a *Medicago sativa* alfalfa line, WL-C290, that has very fast recovery after harvest and excellent standability under sprinkler irrigation (see column 17, lines 37-38)”. The two lines of text in Cluff *et al.* cited by the Examiner state that WL-C290 has “Very fast recovery after harvest and excellent standability

under sprinkler irrigation.” As alluded to by the Examiner, Cluff *et al.* provide no experimental data or evidence to support this statement.

Attached to this Amendment and Response is a Declaration Under 37 C.F.R. § 1.132 by Dr. Jonathan M. Reich (“the Reich Declaration”), an inventor of the present invention and an officer of the assignor. The Reich Declaration provides experimental data to definitively demonstrate that ‘WL-C290’ “is **susceptible** to lodging under sprinkler irrigation” (line spanning pages 2-3; emphasis added). As discussed in the Reich Declaration this “**susceptible**” rating for ‘WL-C290’ is based on the ‘Standability Expression (Lodging Resistance)’ industry standards as established by the North American Alfalfa Improvement Conference (“NAAIC”).

Also attached to the Reich Declaration are the Association of Official Seed Certifying Agencies (“AOSCA”) summary pages for the original certification of the alfalfa variety ‘C-290’ and the amendment for ‘C-290’ when it was re-named as ‘WL 711 WF’. As stated in the Reich Declaration “the breeding history for ‘WL-C290’ as described in these documents does not reference either selection for standability or any measure of standability.”

Based on the lack of any experimental data to support the assertions regarding the standability of ‘WL-C290’ in the Cluff *et al.* patent cited by the Examiner, the complete lack of any support for their assertions in the AOSCA descriptions of ‘WL-C290’, and most importantly in view of the evidence in the Reich Declaration clearly demonstrating that ‘WL-C290’ is susceptible to lodging even under less-than-complete-lodging growing conditions, the Cluff *et al.* reference cannot be prior art to the present invention under either 35 U.S.C. §§ 102 or 103. The Examiner is respectfully requested to withdraw this rejection and issue the pending claims.

CONCLUSION

The Examiner is invited to contact the undersigned if necessary to advance prosecution of this application.

Applicants look forward to allowance of the pending claims or appealing this to the Board of Patent Appeals and Interferences for their consideration of Applicants’ responses to each of the rejections, as discussed above.


The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

Dated: December 12, 2007

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